IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, for their Complaint against defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "DRL" or "Defendants") allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

6. On information and belief, defendant DRL Ltd. is a corporation organized and existing under the laws of India with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

7. On information and belief, defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business located at 107 College Road East, Princeton, NJ 08540.

8. On information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd., and DRL Inc. is controlled by, and acts on behalf of and as the agent for DRL Ltd. with respect to the activities alleged in this Complaint.

9. On information and belief, DRL Ltd. and DRL Inc. acted collaboratively in the preparation and submission of ANDA No. 208318. On information and belief, DRL Inc.'s preparation and submission of ANDA No. 208318 was done at the direction, under the control, for the direct benefit, and on behalf of DRL Ltd.

10. On information and belief, following any FDA approval of ANDA No. 208318, DRL Inc. as well as DRL Ltd. itself and through its subsidiaries and agents, including DRL Inc., will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 208318 throughout the United States, including in the State of Delaware, and/or

import such generic products into the United States for sale and use throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. On information and belief, this Court has personal jurisdiction over DRL Inc.

13. On information and belief, DRL Inc. has admitted that it is subject to personal jurisdiction in this district. *See, e.g., Galderma Labs, L.P. v. Dr. Reddy's Labs. Ltd. et al.*, C.A. No. 15-670, D.I. 13 at ¶ 10 (D. Del.).

14. On information and belief, Defendant DRL Inc. markets, distributes, and/or sells generic drugs within the State of Delaware and throughout the United States.

15. On information and belief, DRL Inc. routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, allopurinol, amlodipine besylate-atorvastatin, amoxicillin, amoxicillin-clavulanate potassium, and anastrozole.

16. On information and belief, DRL Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, allopurinol, amlodipine besylate-atorvastatin, amoxicillin, amoxicillin-clavulanate potassium, and anastrozole.

17. On September 24, 2015, DRL Inc. sent its notice letter pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) to Plaintiffs, including to NPC, which is incorporated in Delaware. On

information and belief, Defendant DRL Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement out of which this suit arises and that has led to foreseeable harm and injury to Plaintiffs, which manufacture Exelon® Patch products for sale and use throughout the United States, including within the State of Delaware. On information and belief, when DRL Inc. committed that tortious act of patent infringement it knew or should have known that NPC is incorporated in Delaware, that NPC and the other Plaintiffs have sued other generic drug makers in Delaware for infringement of the patents asserted herein, and that NPC and the other Plaintiffs could reasonably be expected to sue DRL Inc. in Delaware.

18. On information and belief, DRL Inc., and/or its affiliates are registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesaler" of drug products.

19. On information and belief, this Court has personal jurisdiction over DRL Ltd.

20. On information and belief, Defendant DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) markets, distributes, and/or sells generic drugs within the State of Delaware and throughout the United States.

21. On information and belief, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, ciprofloxacin, allopurinol, amlodipine besylate, atorvastatin calcium, and citalopram.

22. On information and belief, DRL Ltd. (through its wholly-owned subsidiary Defendant DRL Inc.) has agreements with pharmaceutical retailers, wholesalers or

distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, ciprofloxacin, allopurinol, amlodipine besylate, atorvastatin calcium, and citalopram.

23. On September 24, 2015, DRL Ltd. sent its notice letter pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) to Plaintiffs, including to NPC, which is incorporated in Delaware. On information and belief, Defendant DRL Ltd. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement out of which this suit arises and that has led to foreseeable harm and injury to Plaintiffs, which manufacture Exelon® Patch products for sale and use throughout the United States, including the State of Delaware. On information and belief, when DRL Ltd. committed that tortious act of patent infringement it knew or should have known that NPC is incorporated in Delaware, that NPC and the other Plaintiffs have sued other generic drug makers in Delaware for infringement of the patents asserted herein, and that NPC and the other Plaintiffs could reasonably be expected to sue DRL Ltd. in Delaware.

24. On information and belief, DRL Ltd., affiliates of DRL Ltd. and/or subsidiaries of DRL Ltd. are registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy Wholesaler" of drug products.

25. Plaintiffs sell Exelon® Patch products in the State of Delaware.

26. On information and belief, DRL Inc. and DRL Ltd. have applied for FDA approval to market and sell a generic version of Exelon® Patch products throughout the United States, including in Delaware.

27. On information and belief, DRL Inc. and DRL Ltd will market, sell, and offer for sale their proposed generic version of Exelon® Patch products in the State of Delaware following FDA approval of that product.

28. On information and belief, as a result of DRL Inc. and DRL Ltd.'s marketing, selling, or offering for sale of its generic version of Exelon® Patch products in the State of Delaware, Plaintiffs will lose sales of Exelon® Patch products and be injured in the State of Delaware.

29. DRL Inc. and DRL Ltd. have previously submitted to the jurisdiction of this Court and have affirmatively availed themselves of the legal protections of the State of Delaware, having, among other things, asserted counterclaims in this jurisdiction. *See, e.g., Galderma Labs, L.P. v. Dr. Reddy's Labs., Ltd., et al.,* C.A. No. 15-670-LPS (D. Del.); *Allos Therapeutics, Inc. et al. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 14-778-RGA (D. Del.); *Genzyme Corp. et al. v. Dr. Reddy's Labs. Ltd. et al.*, C.A. No. 13-1506-GMS (D. Del).

30. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

31. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the FDA on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

32. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

33. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

34. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the '023 patent is attached hereto as Exhibit A.

35. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

36. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the '031 patent is attached hereto as Exhibit B.

37. The ’023 and ’031 patents were initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

38. On information and belief, Defendant DRL submitted to the FDA an abbreviated new drug application (“ANDA”) under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths (“DRL’s ANDA Products”) before the expiration of the ’023 and ’031 patents.

39. On information and belief, DRL made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the ’023 and ’031 patents are invalid and/or will not be infringed. DRL did not allege that any of the ’023 or ’031 patent claims were unenforceable.

40. Plaintiffs received written notification of DRL’s ANDA and its accompanying 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification by a letter dated September 24, 2015 (“Notice Letter”).

41. This action was commenced within 45 days of receipt of DRL’s Notice Letter.

42. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of DRL’s ANDA Products before the expiration of the ’023 and ’031 patents, DRL has committed an act of infringement under 35 U.S.C. § 271(e)(2).

43. On information and belief, when DRL filed its ANDA, it was aware of the '023 and '031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '023 and '031 patents was an act of infringement of those patents.

44. On information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Products will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

45. On information and belief, the commercial manufacture of DRL's ANDA Products will involve direct infringement of the '023 patent. On information and belief, this will occur at DRL's active behest, and with DRL's intent, knowledge, and encouragement. On information and belief, DRL will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '023 patent.

46. On information and belief, the commercial manufacture of DRL's ANDA Products will involve direct infringement of the '031 patent. On information and belief, this will occur at DRL's active behest, and with DRL's intent, knowledge, and encouragement. On information and belief, DRL will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

47. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to DRL's ANDA Products be a date that is not earlier than January 8, 2019, the expiration date of the '023 and '031 patents, and an award of damages for any commercial sale or use of DRL's ANDA Products and any act committed by DRL with respect to the subject matter claimed in the '023 and '031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

48. On information and belief, DRL has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Products, including seeking approval of those products under DRL's ANDA.

49. There is a substantial and immediate controversy between Plaintiffs and DRL concerning the '023 and '031 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that DRL will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that DRL has infringed and induced infringement of one or more claims of the '023 and '031 patents by filing the aforesaid ANDA relating to DRL's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths;

B. A permanent injunction restraining and enjoining DRL and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, as claimed in the '023 and '031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to DRL's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, be a date that is not earlier than the expiration of the right of exclusivity under the '023 and '031 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, will infringe one or more claims of the '023 and '031 patents and that DRL will induce infringement of one or more claims of the '023 and '031 patents;

E. Damages from DRL for the infringement and inducement of infringement of the '023 and '031 patents;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: November 5, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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